

(19) **DANMARK**



Patent- og
Varemærkestyrelsen

(12)

Oversættelse af europæisk patentskrift

(10) **DK/EP 2835100 T3**

-
- (51) Int.Cl.: **A 61 B 5/0205 (2006.01)** **A 61 B 5/00 (2006.01)** **A 61 B 5/0402 (2006.01)**
A 61 B 5/1455 (2006.01)
- (45) Oversættelsen bekendtgjort den: **2016-02-22**
- (80) Dato for Den Europæiske Patentmyndigheds bekendtgørelse om meddelelse af patentet: **2015-11-18**
- (86) Europæisk ansøgning nr.: **14176602.2**
- (86) Europæisk indleveringsdag: **2014-07-10**
- (87) Den europæiske ansøgnings publiceringsdag: **2015-02-11**
- (30) Prioritet: **2013-08-07 US 201313961441**
- (84) Designerede stater: **AL AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HR HU IE IS IT LI LT LU LV MC MK MT NL NO PL PT RO RS SE SI SK SM TR**
- (73) Patenthaver: **DynoSense Corp., 100 Century Center Court Suite 650 San Jose CA 95112, USA**
- (72) Opfinder: **Azimi, Saeed, 113 Madera Ct., Los Gatos, CA 95032, USA**
- (74) Fuldmægtig i Danmark: **Awapatent A/S, Rigsgade 11, 1316 København K, Danmark**
- (54) Benævnelse: **System til at måle og optage en brugers livstegn**
- (56) Fremdragne publikationer:
US-A- 4 407 295
US-A- 5 509 422
US-A1- 2005 014 999
US-A1- 2013 035 602
US-B1- 6 712 762
TAASAN ET AL: "Alcohol increases sleep apnea and oxygen desaturation in asymptomatic men.", THE AMERICAN JOURNAL OF MEDICINE, vol. 71, no. 2, 1 August 1981 (1981-08-01) , pages 240-245, XP055132240, ISSN: 0002-9343
WAKAKO TSUTSUMI ET AL: "Influence of alcohol on respiratory disturbance during sleep", PSYCHIATRY AND CLINICAL NEUROSCIENCES, vol. 54, no. 3, 1 June 2000 (2000-06-01), pages 332-333, XP055132243, ISSN: 1323-1316, DOI: 10.1046/j.1440-1819.2000.00701.x

DESCRIPTION

BACKGROUND

[0001] The embodiments herein relate generally to systems for measuring and recording a body's vital signs such as blood oxygen levels, respiratory characteristics, heart electrical signatures (electrocardiography or ECG), heart rate, blood pressure and temperature for health monitoring applications.

[0002] Currently there exist several systems that use multiple sensors connected to a single base unit, which is able to collectively measure all vital signs. These integrated units still require a user to connect two or more sensors to a particular location on the body. For example, a conventional pulse oximetry system used for the measurement of blood oxygen comprises a sensor attached to a user's finger, an oral thermometer requires placement under the tongue or arm, an infrared thermometer is placed in the ear canal, an ECG sensor requires two probes placed across the heart, and most blood pressure monitors use either auscultatory or oscillometric methods, which require a cuff to be worn on the user's arm. These systems have limitations because they are bulky or heavily power dependent and/or they require multiple attachments and actions by the user in order to measure and record the vital signs data.

[0003] Document US 2013/0035602 discloses an ethanol level sensor that discloses the measurement of breath flow and ECG at the same time during a single action of a user. Document US 2005/0014999 discloses a cable-free vital sign monitoring device that enables the measurement of temperature, PPG and electrical signals simultaneously.

[0004] As such, there is a need in the industry for a system that can detect and record all critical vital signs with a single action by the user.

SUMMARY

[0005] The object of the present invention is achieved by a system as disclosed by independent claim 1.

[0006] A system for measuring and recording data pertaining to a user's vital signs in response to a single action by the user, the system being configured to analyze and communicate the data to a remote location is provided. The system comprises a base unit comprising a computer system, metallic layers affixed to a first side face and a bottom face of the base unit, an aperture, and a flexible shaft extending from the bottom face of the base, and an extension member pivotably mounted to a second side face of the base unit, wherein the system is configured to receive the user's thumb on the metallic layer located on the first side face, index finger between the base unit and the extension member, lips on the bottom face metallic layer and tongue above the flexible shaft to capture the vital signs data and communicate the data to the remote location.

BRIEF DESCRIPTION OF THE FIGURES

[0007] The detailed description of some embodiments of the invention will be made below with reference to the accompanying figures, wherein the figures disclose one or more embodiments of the present invention.

FIG. 1 depicts a perspective view of certain embodiments of the invention;

FIG. 2 depicts a perspective view of certain embodiments of the invention;

FIG. 3 depicts a side view of certain embodiments of the invention in use;

FIG. 4 depicts a block diagram of a computer system of certain embodiments of the invention;

FIG. 5 depicts a side view of certain embodiments of the invention in use;

FIG. 6 depicts a front view of certain embodiments of the invention in use;

FIG. 7 depicts an electrocardiography waveform analyzed in certain embodiments of the invention;

FIG. 8 depicts a series of electrocardiography waveforms analyzed in certain embodiments of the invention;

FIG. 9 depicts a perspective view of certain embodiments of the invention; and

FIG. 10 depicts a perspective view of certain embodiments of the invention.

DETAILED DESCRIPTION OF CERTAIN EMBODIMENTS

[0008] FIGS. 1-3 depict certain embodiments of the system for measuring a user's vital signs. The system 100 comprises a base unit comprising aperture 101, extension member 102, interior housing 103 comprising a computer system, contoured metallic pad 104, sensing tip 105, base unit extension 201, tongue resting area 203, flexible shaft 204, aperture (air opening) 206, air shaft 207, bottom metallic layer 208 and touch screen 307. Extension member 102 may be pivotably mounted to base unit extension 201 by any known components in the field such as a compression spring.

[0009] In certain embodiments of the invention, a first LED device is attached to extension member 102 and a second LED device is attached to base unit extension 201. These LED devices may comprise any known components in the field such as lights or detectors, which may comprise photoplethysmographs (PPG) or plethysmographs. One common use of photoplethysmography can be found in pulse oximeters, which determine the oxygen saturation of arterial blood and measures the change in the volume of arterial blood with each pulse beat. Pulse oximeter devices contain two light emitting diodes: one in the red band of light (660 nanometers) and one in the infrared band of light (940 nanometers). Oxyhemoglobin absorbs infrared light while deoxyhemoglobin absorbs visible red light. Pulse oximeter devices also contain sensors that detect the ratio of red/infrared absorption several hundred times per second. A preferred algorithm for calculating the absorption is derived from the Beer-Lambert Law, which determines the transmitted light from the incident light multiplied by the exponential of the negative of the product of the distance through the medium, the concentration of the solute and the extinction coefficient of the solute.

[0010] FIG. 4 depicts the computer system, which comprises PCB-Unit 400, processor 401, Analog Front End (AFE) unit 402, which provides analog filtering, biasing and digitization of Air-Flow Sensor 403, which detects the user's breathing and acoustic sounds from the body. AFE unit 402 also provides analog filtering, biasing and digitization of ECG and Temperature Pads 404 located at metallic pad 104 and bottom metallic layer 208. LED-Controller unit 408 provides filtering, biasing and digitization of LED-Light 405 and LED-Detector 406 placed on extension member 102 and base unit extension 201, or vice versa, for detecting data related to a photoplethysmograph (PPG). Battery-Controller unit 409 provides power for all electronics of the system from battery source 407. RF-Controller 410 provides a wireless connection for transmitting and receiving data to system 100. LCD-Controller 411 displays information and receives an input from a user on touch screen 307.

[0011] FIGS. 3 and 5-6 depict certain embodiments of the invention in use. A user 500 uses left hand 300 to hold system 100. The user's left thumb 301 is placed on contoured metallic pad 104 and left index finger 306 is placed between extension member 102 and base unit extension 201. System 100 is placed inside the user's mouth while held by left hand 300 such that sensing tip 105 on flexible shaft 204 is under the user's tongue below air shaft 207 with the tongue touching (or resting) on tongue resting area 203. In this position, air opening 206 is above the user's tongue and the lips are placed on bottom metallic layer 208 such that breathing is accomplished through the user's nose via air rushing through apertures 101 and 206.

[0012] In this setup, the computer system of system 100 senses electrical signals between thumb 301 placed on metallic pad 104 and bottom metallic layer 208 to construct an ECG signal as shown in FIG. 7. The computer system then calculates all heart related data from the ECG signal of FIG. 7, also referred to as a "QRS" complex wave. As the user breathes, the flow of air is sensed by the computer system by the amount of air rushing in and out of apertures 101 and 206, therefore yielding respiratory data. Sensing tip 105 measures the user's body temperature under the tongue. The LED detector measures data related to a PPG based on the reflection of LED light when the user's left index finger 306 is placed between extension member 102 and base unit extension 201. In this configuration, the index finger is placed between LED-Light 405 and LED-Detector 406.

[0013] From constructed ECG signal 800 and PPG signal 802 it is then possible to construct the Pulse Transit Time ("PTT") shown in FIG. 8. PTT, defined as the transit time for a pressure pulse launched by a heartbeat in a patient's arterial system, has been shown in the prior art to correlate to both systolic and diastolic blood pressure. The QRS complex 800 indicates an initial depolarization of ventricles within the heart and, informally, marks the beginning of the heartbeat 801 and a pressure pulse that follows. Pulse oximetry is measured as described above on the user's left index finger. Time-dependent features of the optical waveform indicate both pulse rate and a volumetric absorbance change in an underlying artery in the finger caused by the propagating pressure pulse.

[0014] PTT measurements determine the time separating a maximum point on the QRS complex (indicating the peak of ventricular depolarization) 801 and a foot of the optical waveform 804 (indicating beginning of the pressure pulse) with 803 indicating the trailing end. PTT depends primarily on arterial compliance, the propagation distance of the pressure pulse (which is closely approximated by the patient's arm length 603 or 604), and blood pressure. To account for patient-dependent properties, such as arterial compliance, PTT-based measurements of blood pressure are 'calibrated' using a conventional blood pressure cuff. During the calibration process the blood pressure cuff is applied to the patient, used to make one or more blood pressure measurements, and then removed. Going forward, the calibration blood pressure measurements are used, along with a change in PTT, to determine the patient's blood pressure and blood pressure variability. PTT typically relates inversely to blood pressure, i.e., a decrease in PTT indicates an increase in blood pressure.

[0015] In certain embodiments of the invention, the vital signs data is displayed to the user on touch screen 307. In FIG. 9, cradle unit 900 charges system 100, cleans and sterilizes the system after each use. Cradle unit 900 can interact with a user using various LED colors 907, 908, 909 or 910, press button 906, as well as via voice command with built-in speaker and microphones 911. Furthermore, unit 900 has a wireless (Wi-Fi) or wired connection (Ethernet) to the Internet, which allows system 100 to communicate using short wavelength frequencies such as Bluetooth Radio. This configuration allows for a two way communication of cloud-based computer applications with system 100. Therefore, system 100 can transmit all vital signs data to the Internet and receive new programming from external cloud applications. Cradle unit 900 can also optionally communicate with other devices such as a weight scale, blood test kits, blood pressure cuff or other medical appliances.

[0016] Cradle unit 900 gets power from wall outlet 901. A user places system 100 inside cradle unit 900 after each use by lifting lid 904 around pivot point 903. Optionally, there is activity tracking unit 902 that is also part of cradle unit 900. Referring to FIG. 10, activity tracker unit 902 comprises top face 1000, a motion sensor that is attached to the user's body using clips 1004 with pivot point 1003 and 1001 preferably on an undershirt for men and a bra-strap for women. The activity tracker unit 902 is charged using cradle unit 900 by being placed inside a slot in the cradle unit 900 via access ports 1005. The activity tracker also communicates with cradle unit 900 wirelessly. It shall be appreciated that activity tracker unit 902 may collect additional data about the user's body and/or activities.

[0017] In operation, as shown in FIG. 6, user 500 removes system 100 from cradle unit 900 (typically after brushing their teeth or at other times), and places it in the mouth with left hand 300 while relaxing right hand 604 typically in standing position while left arm 603 is in a bent position. The computer system calculates and captures all body vital signs accurately, typically in less than 30 seconds when an audible sound is heard instructing the user to remove system 100 from the mouth. System 100 is then washed and placed back into cradle unit 900. The user can selectively review the data on touch screen 307 or visit a website by logging into an account and reviewing the data.

[0018] In one embodiment, the system generates alerts and alarms if it detects that any values of the vital signs are outside the normal limits. The system may generate messages (e.g., email or SMS messages) containing such information to be sent to the doctor, the user, and/or any such person chosen by the user.

[0019] In an alternative embodiment, system 100 has access to body saliva samples during operation of sensing vital signs. Body saliva is similar to blood in many ways and therefore detectors can be developed to obtain, analyze and detect other non-vital sign data about the body such as glucose level, influenza A or B, alcohol or drug levels and DNA analyses.

[0020] It shall be appreciated that the components of the system described in several embodiments herein may comprise any known materials in the field such as metals and molded plastics, and be of any color, size and/or dimensions.

[0021] Persons of ordinary skill in the art may appreciate that numerous design configurations may be possible to enjoy the functional benefits of the inventive systems. Thus, given the wide variety of configurations and arrangements of embodiments of the present invention the scope of the invention is reflected by the breadth of the claims below rather than narrowed by the embodiments described above.

REFERENCES CITED IN THE DESCRIPTION

This list of references cited by the applicant is for the reader's convenience only. It does not form part of the European patent document. Even though great care has been taken in compiling the references, errors or omissions cannot be excluded and the EPO disclaims all liability in this regard.

Patent documents cited in the description

- US20130035602A [0003]
- US20060014999A [0003]

P A T E N T K R A V

1. System til at måle og gemme data vedrørende en brugers vitale tegn, som respons på en enkelt handling af brugeren, hvor systemet er indrettet til at analysere og kommunikere dataet til en fjern position, hvor systemet omfatter:
5 en grundenhed, der omfatter et computersystem, metallag, som er vedhæftet på en første sideflade og bundflade af grundenheden, til at måle elektriske signaler for at danne et ECG, en åbning til at måle luftstrømning, og et fleksibelt skaft, der udstrækker sig fra bundfladen af grundenheden, hvor skaftet har en målespids til at måle temperatur; og
10 et forlængelseselement til pletysmografi, der er pivoterbart monteret på en anden sideflade af grundenheden;
hvor systemet er indrettet til simultant at modtage brugerens venstre tommelfinger på metallaget, som er placeret på den første sideflade, venstre pegefinger mellem grundenheden og forlængelseselementet, læber på bundflademetallaget og tungen over det fleksible skaft for at opsamle dataet om de vitale tegn og kommunikere dataet til den fjerne position.
2. System ifølge krav 1, hvor systemet yderligere omfatter et display, der er indrettet til at modtage et input fra brugeren og fremvise dataet om de vitale tegn til brugeren.
20
3. System ifølge krav 1, hvor forlængelseselementet omfatter en lysudsendende diodeindretning, der er indrettet til at blive anvendt som en pletysmograf.
4. System ifølge krav 1, hvor computersystemet er indrettet til at sende en advarsel til en entitet, hvis nogle værdier i dataet om brugerens vitale tegn er uden for normale grænser.
25
5. System ifølge krav 1, hvor computersystemet genererer et elektrokardiografisignal baseret på de elektriske signaler, som måles af metallagene.
6. System ifølge krav 1, hvor computersystemet måler luftstrømning gennem åbningen baseret på brugerens åndedræt og genererer respirationsdata baseret på den målte luftstrømning.
30
7. System ifølge krav 1, hvor systemet yderligere omfatter en detektor, der er indrettet til at måle og optage data, som vedrører brugerens ikke-vitale tegn, valgt blandt glucoseniveau, influenza A eller B, alkohol- eller rusmiddelniveauer og DNA-analyser.
- 35 8. System ifølge krav 1, hvor systemet yderligere omfatter opbevaringsenhed, der er indrettet til at opbevare, rense og sterilisere grundenheden og forlængelseselementet.
9. System ifølge krav 8, hvor systemet yderligere omfatter en aktivitetstrackerenhed, der er indrettet til at opsamle data vedrørende brugerens aktivitet.

10. System ifølge krav 8, hvor opbevaringsenheden omfatter en kommunikationsindretning, som er indrettet til trådløst at kommunikere dataet om vitale tegn til den fjerne position og andre indretninger.

DRAWINGS

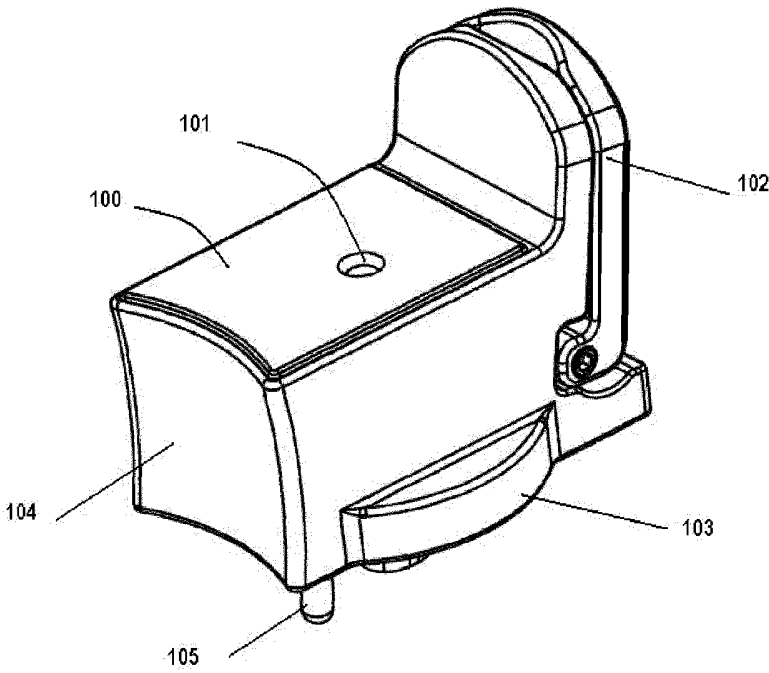


FIG. 1

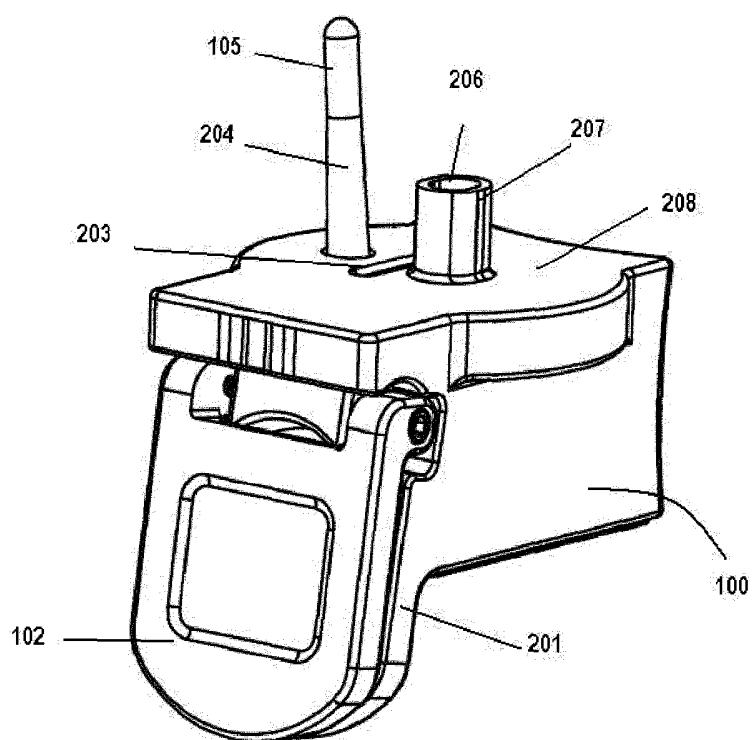


FIG. 2

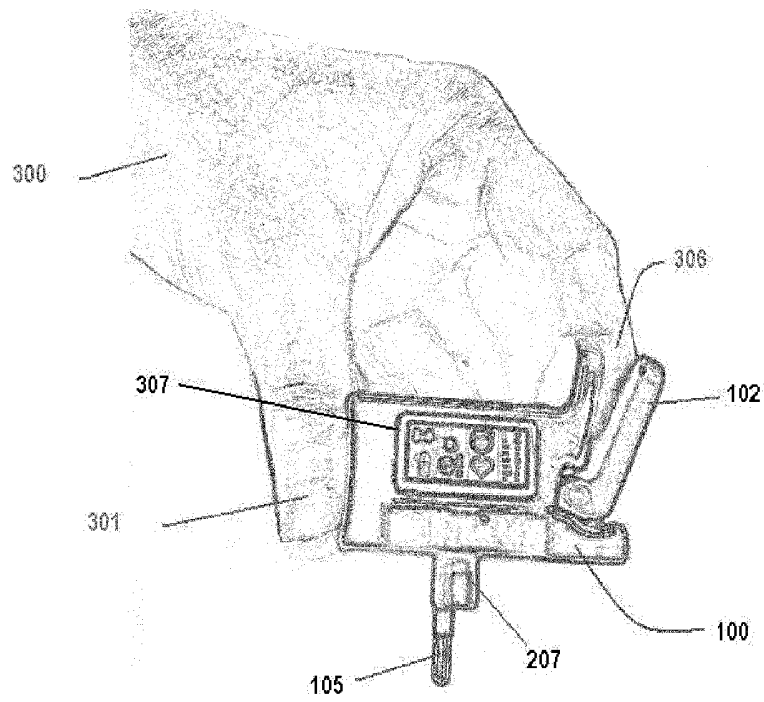
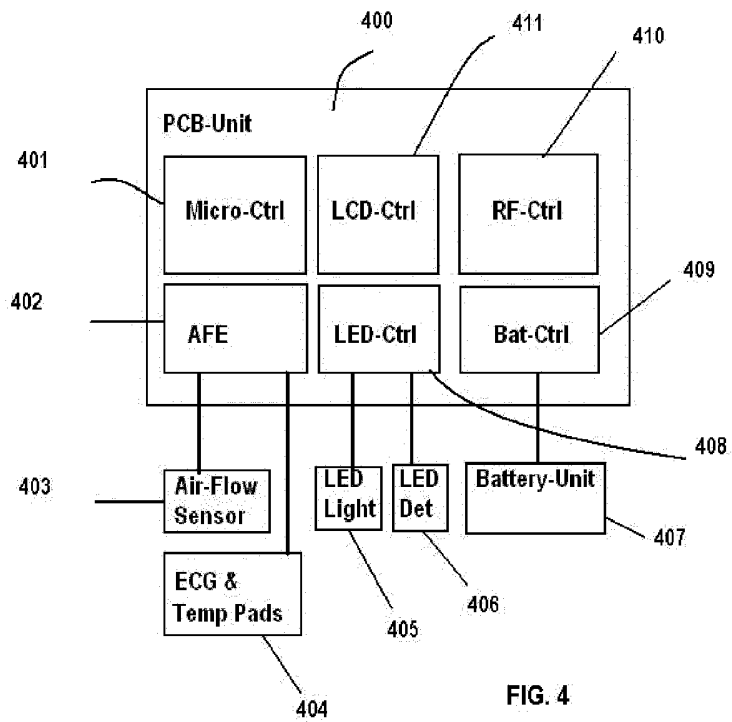


FIG. 3



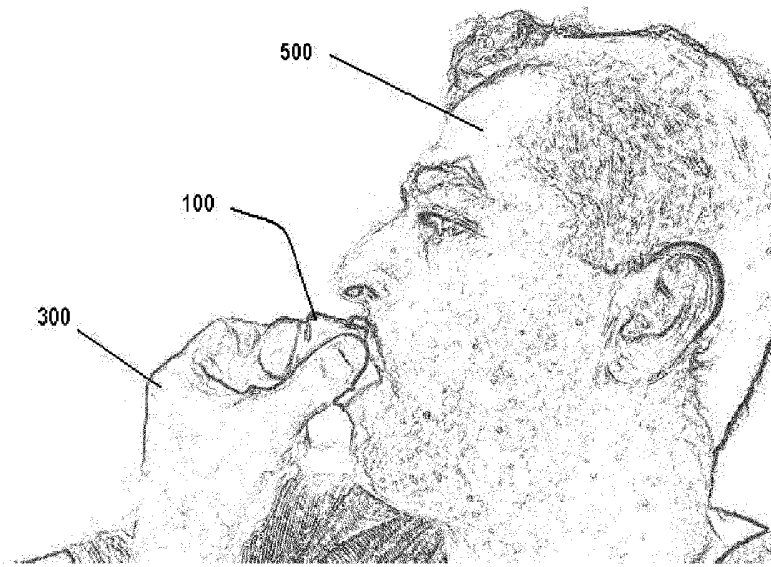


FIG. 5

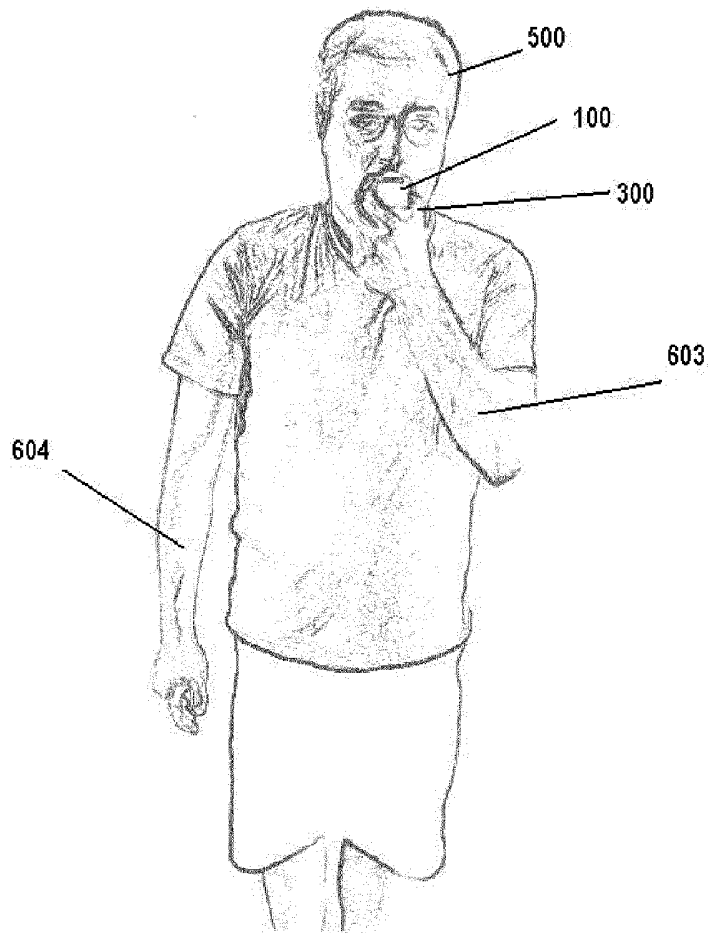


FIG. 6

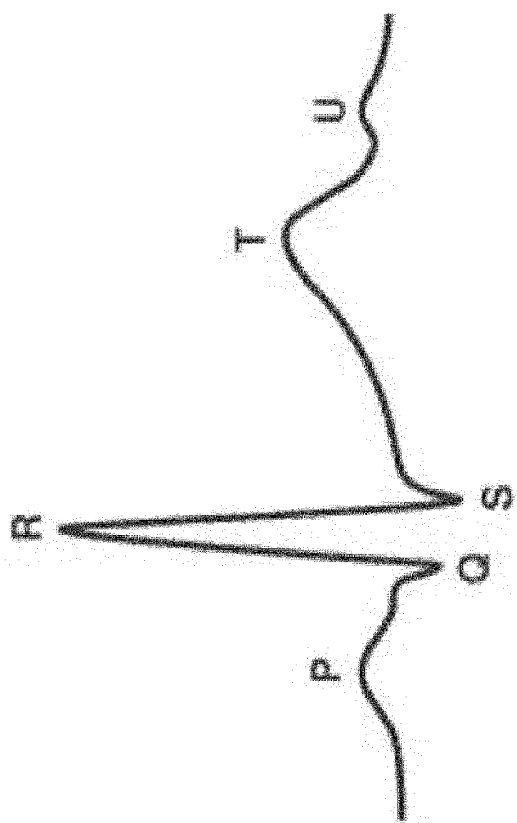


FIG. 7

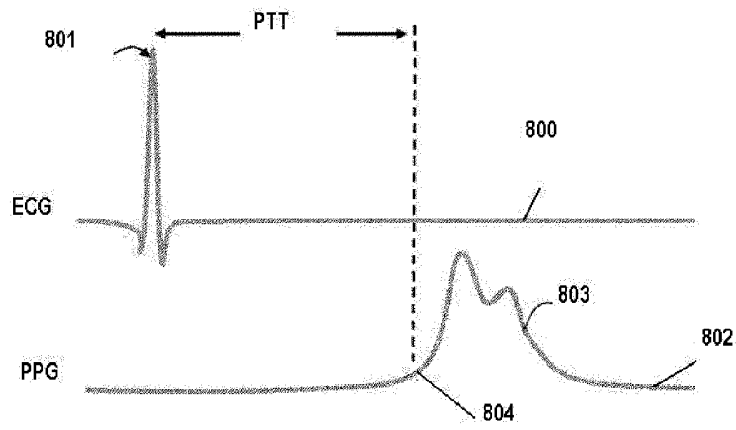


FIG. 8

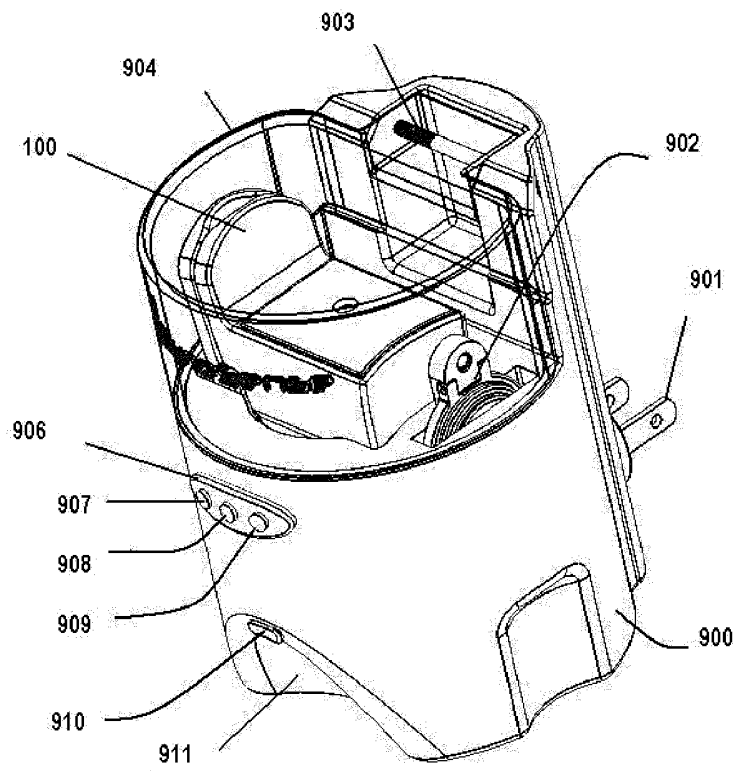


FIG. 9

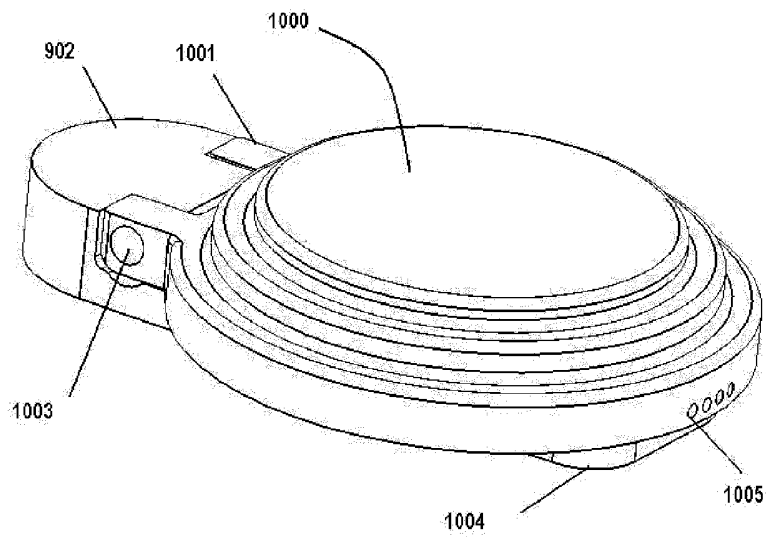


FIG. 10